No. 17-290

IN THE
Supreme Court of the United States

MERCK SHARP & DOHME CORP.,
Petitioner,

v.

DORIS ALBRECHT, ET AL.,
Respondents.

On Writ of Certiorari
to the United States Court of Appeals
for the Third Circuit

BRIEF OF TORT LAW PROFESSORS JOHN C. P. GOLDBERG AND BENJAMIN C. ZIPURSKY AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICI CURIAE*[1]

John C.P. Goldberg is the Carter Professor of General Jurisprudence at Harvard Law School. Benjamin C. Zipursky is the James H. Quinn '49 Professor in Legal Ethics at Fordham Law School. *Amici* are co-authors on a leading casebook, TORT LAW: RESPONSIBILITIES AND REDRESS (4th ed. 2016), and of a condensed treatise, THE OXFORD INTRODUCTIONS TO U.S. LAW: TORTS (2010). They have also authored dozens of articles and book chapters on tort law, including products liability and preemption. Their writings focus on the nuts and bolts of doctrine, as well as history and theory, emphasizing – in contrast to economic- and justice-based approaches – the traditional American understanding of tort as law that defines injurious wrongs and empowers victims to obtain a civil form of redress from those who wrongfully injure them.

Amici have no stake in the outcome of this case other than their academic interest in the rational development of the law. They have serious concerns that the rule proposed by Petitioner in this case, if adopted by the Court, would constitute an intrusion into state tort law that is unnecessary to give full effect to the Supremacy Clause, at odds with basic principles of federalism, and inconsistent with our legal and political traditions, which have always recognized the right of victims of legally recognized, injurious wrongs to an avenue of civil recourse against wrongdoers through state common law.

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[1] Pursuant to Supreme Court Rule 37.6, counsel for *Amici* represent that they (and *Amici*) authored this brief in its entirety and that none of the parties or their counsel, nor any other person or entity other than *Amici* or their counsel, made a monetary contribution intended to fund the preparation or submission of this brief. Pursuant to Rule 37.3(a), counsel for *Amici* also represent that all parties have consented to the filing of this brief.

SUMMARY OF ARGUMENT

Federal preemption of tort law involves the recognition that state common law must give way to federal regulatory law when federal law expressly displaces state law or when there is an actual conflict between them. Yet because, within our federal system, the common law of torts overwhelmingly is the province of the states, this Court has been careful to treat the federal regulatory domain and the state common law domain as largely complementary, not conflicting.

Similarly, this Court has avoided unduly interfering with state tort law even where legitimate constitutional concerns have justified setting certain limits on it, as in the law of defamation and punitive damages. In the area of preemption, this pattern continued in *Wyeth v. Levine*, 555 U.S. 555 (2009), in which the Court found no preemption of failure-to-warn claims involving brand-name drugs. Petitioner now attempts an end-run around *Levine* by arguing that FDA's rejection of Petitioner's proposed label demonstrates that it was "impossible" for Petitioner to give the adequate warnings required to avoid tort liability. Given the absence of any statutory prohibition on Petitioner's ability to issue enhanced warnings of newly discovered medical risks, and given that Petitioner's proposed warning contained deficiencies in the dimensions of adequacy that state law deems significant (deficiencies that FDA also recognized in its rejection), the Court should not credit this argument. Indeed, it cannot do so without adopting an unstructured, expansive notion of "impossibility" that would efface the line between legitimately ensuring that state tort law operates within constitutional confines and illegitimately undertaking to fashion a general common law of failure-to-warn liability.

An examination of failure-to-warn law for prescription drugs reveals that Petitioner is asking the Court for an unnecessary and inappropriate displacement of state law. Whether a warning is adequate involves considerations such as the nature and magnitude of the risk and the clarity and communication of the warning. The warning proposed by Petitioner was almost certainly not adequate as a matter of law, and in any event posed a fact issue for resolution at trial. FDA's rejection of Petitioner's understated and muddled warning in no way indicates that the agency would have rejected a warning of the risk of atypical femoral fractures that was adequate in the relevant dimensions. Indeed, FDA's rejection of a proposed warning in *Levine* (which this Court found had no preemptive effect) was considerably stronger than the proposal rejected by FDA in this case, thus underscoring the insufficiency of Petitioner's showing. There is no indication in this case that FDA's "rejection" foreclosed an attempt to add a warning that would be adequate under state law. In short, it was entirely possible for Petitioner to comply with both federal and state law by simply proposing or adding an adequate warning.

Finally, Petitioner's dire prediction that, without further federal court oversight, state law will thwart federal regulations by allowing juries to run wild is simply overblown. Insofar as juries hearing failure-to-warn claims against Petitioner will be required to answer a "counterfactual" question about whether FDA would have approved an adequate warning, this is the sort of thing juries are entrusted to do every day. Moreover, they do it in a context that has significant, existing protections to ensure proper deference to prescribing physicians' expertise and appropriate

judgments by FDA, and to ensure the reliability of the scientific evidence presented to them. The learned intermediary rule, the defense of regulatory compliance, and trial judges' screening of proposed expert testimony are robust protections against overreach. These and other checks built into the operation of state tort law are more than sufficient to negate any need for further federal court oversight.

ARGUMENT

I. RESPECT FOR STATE TORT LAW REQUIRES A RESTRAINED APPROACH TO IMPLIED PREEMPTION ANALYSIS

Petitioner, the manufacturer of a brand-name prescription drug, seeks to persuade this Court that it deserves to win failure-to-warn claims brought against it without any determination as to the adequacy of the warnings it issued. It claims that the doctrine of "impossibility" preemption allows for such a result. However, unlike defendants who raise *express* preemption arguments, as well as those who raise implied preemption arguments that turn on clear statutory text – *see PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011) (Hatch-Waxman Act's prohibition on unilateral label changes by generic drug manufacturers makes it impossible for them to comply with conflicting state-law requirements) – Petitioner's implied preemption argument has no statutory anchor whatsoever. If the Court accepts Petitioner's invitation to craft an impossibility- based escape-hatch from state tort liability, it will be cutting too deeply into state tort law without a sufficient federal basis.

The application of implied preemption doctrine untethered from any guiding text carries a great risk of undermining federalism values. That is the principal

reason for submitting this *Amicus* brief. With no text to control the determination of federal preemption in this case, the degree to which state common law remains available to provide redress to victims of injurious misconduct depends entirely on this Court and lower federal courts exercising self-restraint.

This brief does not challenge the federal courts' authority to engage in implied preemption analysis. It does, however, point out that the approach to implied preemption that would be necessary for the Court to rule for Petitioner in this case presupposes a conception of that authority that is inconsistent with its role within a federalist system. Crafting the rules that federal judges prefer, rather than applying the common law of the state, would mark a return to the days of *Swift v. Tyson*, 41 U.S. (16 Pet.) 1 (1842). Basic principles of federalism and *Erie Railroad Co. v. Tompkins*, 304 U.S. 64 (1938), call for great caution.

This is not the first time that state common law has been imperiled by tort litigation that found its way to the Supreme Court. Constitutional attacks on defamation law and punitive damages awards have cut deeply into these areas of state law – sometimes too deeply, as has been observed by many Justices, including Chief Justice Rehnquist, as well as Justices Ginsburg, Scalia, Thomas, and White. In those areas – following *New York Times Co. v. Sullivan*, 376 U.S. 254 (1964), and *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996) (respectively) – the Court eventually chose to reject aggressive construction of pro-defendant constitutional protection in order to remain true to its federalist commitments. That is what it should do here, too.

A few examples will illustrate the present point. *New York Times Co. v. Sullivan* remains emblematic

of the Court's power and obligation to ensure tort law operates within constitutional boundaries. The advertisement at issue in *Sullivan* did not mention any individual official, yet the plaintiff, a city commissioner, brought suit and won a huge punitive damages verdict. In these circumstances, the Court looked past the form of the litigation and identified it for what it really was – a seditious libel prosecution. It rightly shielded the New York Times from tort liability under the First Amendment.

Sullivan's progeny tell a different story. Media defendants pressed for "elaboration" of *Sullivan*'s holding. The Court soon articulated a sprawling constitutional jurisprudence. In the eyes of some Justices, the Court's burgeoning case law threatened to run afoul of *Erie* and its federalist underpinnings. Most notably, in *Gertz v. Robert Welch, Inc.*, 418 U.S. 323 (1974), Justice White penned an impassioned dissent, arguing that the Court was experiencing substantial mission creep:

> For some 200 years – from the very founding of the Nation – the law of defamation and right of the ordinary citizen to recover for false publication injurious to his reputation have been almost exclusively the business of state courts and legislatures. . . .
>
> But now, using [the First] Amendment as the chosen instrument, the Court, in a few printed pages, has federalized major aspects of libel law by declaring unconstitutional in important respects the prevailing defamation law in all or most of the 50 States.

Id. at 369-70 (White, J., dissenting).

Regardless of whether one agrees with Justice White that *Gertz* would have been the right moment to stem the expansion of federal defamation law, he was surely right to sound a cautionary note. His warning was eventually heeded. Sixteen years after *Gertz*, media defendants asked the Court to hold that the First Amendment precluded tort liability for anything that could be characterized as a statement of opinion. It declined. Writing for a 7-2 majority in *Milkovich v. Lorain Journal Co.*, 497 U.S. 1, 20-21 (1990), Chief Justice Rehnquist recognized that there was already opinion protection within state common law, that powerful First Amendment liability limits had already been crafted by the Court, and that the analytical case for a new and broad additional federal-law shield simply did not hold up to scrutiny. The Court had done enough to ensure that state defamation law operated with proper respect for rights of free speech; doing more would threaten to efface the line between constitutional law and general common law.

A similar pattern has unfolded in the constitutional law of punitive damages, in which federalist concerns have been flagged from the start. In *BMW of North America, Inc. v. Gore*, the majority identified a "notice" problem with a $2 million punishment for nondisclosure of an invisible flaw in the paint of a luxury car. 517 U.S. at 574. In their dissents, Justice Scalia and Justice Ginsburg contended that the Court had allowed the anomalousness of the punitive damages claim in that particular case to spawn an analytically unsound doctrine that cut unduly into state common law. *See id.* at 605 (Scalia, J., joined by Thomas, J., dissenting); *id.* at 612 (Ginsburg, J., joined by Rehnquist, C.J., dissenting).

The defense victory in *Gore* gave litigants an incentive to press to federalize state punitive damages law. A majority of the Justices continued to respond, with the high-water mark being set by *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003), which once again garnered dissenting opinions. *See id.* at 429 (Scalia, J., dissenting); *id.* at 429-30 (Thomas, J., dissenting); *id.* at 430 (Ginsburg, J., dissenting). In the years following *Campbell*, the Court received numerous certiorari petitions encouraging it to set a hard-and-fast numeric ratio of punitive to compensatory damages, even in cases involving wrongful death or massive environmental harm.

In part through denial of petitions, the Roberts Court halted the development of constitutional-excessiveness doctrine in punitive damages law. In *Exxon Shipping Co. v. Baker*, 554 U.S. 471 (2008), the Court denied Exxon's certiorari petition on constitutional excessiveness, *Exxon Shipping Co. v. Baker*, 552 U.S. 989 (2007) (mem.) (granting certiorari only on other issues in the case), and used its unquestioned authority in federal maritime law to decide the case on other grounds. In *Phillip Morris USA Inc. v. Williams*, 556 U.S. 178 (2009), the Court repeatedly declined to address the constitutional-excessiveness issue and ultimately permitted a very large Oregon punitive damages verdict to stand. In light of the dissenting opinions over the years of Justices Thomas and Ginsburg (and the clear choice of Justice Breyer to utilize procedural, not substantive excessiveness, concepts), the halting of constitutional-excessiveness decisions can be seen as a deliberate, federalist-inspired effort to respect state tort law through restraint and analytical rigor.

Preemption law presents parallel issues of restraint, as the various Justices' opinions on preemption vividly display. The font of modern preemption jurisprudence as it relates to tort law is an express preemption case rather than an implied preemption case. In *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), a majority of the Justices concluded that Congress's adoption of highly specific statutory warnings for cigarettes preempted state failure-to-warn claims, but not other claims, including for fraud. Ever since, members of the Court have articulated worries that defense arguments have sometimes succeeded when restraint and respect for state tort law might have been the better path.

From a (concededly academic) perspective, *Wyeth v. Levine*, 555 U.S. 555 (2009), can be seen as having drawn a line in the sand based on recognition of post-*Erie* limits on the federal courts' lawmaking authority. Even though of course interpreting a different constitutional provision, the Court's *Levine* ruling resembled its refusal to constitutionalize opinion protection in *Milkovich* and its resistance to fixing rigid rules for constitutional excessiveness in *Williams* and *Exxon*. Preemption of all failure-to-warn claims for FDA-approved drugs was for drug manufacturers the brass ring, but six Justices decided that close analysis of the statutory and regulatory framework did not justify the ruling Wyeth sought. Moreover, as Justice Thomas observed in his concurrence, an expansive implied preemption doctrine threatened to undercut the authority of the states to fashion rules of tort law. Although Justice Thomas concluded two years later in *Mensing* that impossibility preemption applies to claims against *generic* drug manufacturers, that result was driven by the clear language of the Hatch-Waxman Act and

the absence of a counterpart in it to the CBE provision relied upon in *Levine*.

In its briefs before the Court in this case, Petitioner is taking another shot at eliminating a broad range of failure-to-warn claims against manufacturers of brand-name drugs, hoping that what the Court was unwilling to do in *Levine* it might do today in a slightly different form. But the Court was right to reject impossibility preemption in *Levine* because it would have undermined the states' traditional power to provide redress to those who can prove their common law claims. Having shown restraint a decade ago to preserve this domain of state sovereignty and individual rights, the Court should not reverse course now, on what is (as Respondents' brief and the discussion below show) a much weaker set of facts.

Unfortunately, Petitioner's brief does not provide the Court with a basic model of the workings of the state failure-to-warn law that it would be displacing were it to find preemption. It similarly overlooks the range of doctrinal and statutory resources that state tort law currently supplies to prescription drug manufacturers to protect them from unwarranted liability and litigation. Parts II and III, *infra*, aim to plug these gaps.

II. PETITIONER'S PREEMPTION ARGUMENT WOULD REQUIRE THIS COURT TO INTERFERE UNDULY WITH A CORE AREA OF STATE TORT LAW

Understanding failure-to-warn law in the pharmaceutical context is a necessary prelude to analyzing Petitioner's preemption argument. When one does so, however, the weakness of that argument becomes evident.

A. Failure-To-Warn Law Provides the Primary Line of Defense Against Unduly Dangerous Prescription Drugs by Requiring Manufacturers To Warn Adequately of Dangerous Side-Effects

Redressing injuries caused by improperly labeled medicines has long been a central concern of state tort law. Indeed, the landmark decision of *Thomas v. Winchester*, 6 N.Y. 397 (1852), was such a case. *Thomas* in turn set the stage for then-Judge Cardozo's decision in *MacPherson v. Buick Motor Co.*, 111 N.E. 1050 (N.Y. 1916), which is widely regarded as the font of modern products liability law. Requiring commercial sellers of drugs properly to warn of their products' hidden dangers is and has always been central to state tort law.

Modern products liability law focuses on whether a product that has injured a consumer left the seller's hands in a defective condition because of a design defect, a manufacturing defect, or a failure to warn. Because products often cannot be designed in a way that eliminates their dangers without destroying their benefits, in many cases what determines whether a product is unduly dangerous are the warnings and instructions that accompany it. Just as they count on manufacturers to adopt non-defective designs, product users justifiably rely on manufacturers to provide adequate warnings. And just as design-defect law requires manufacturers to refrain from adopting unreasonably dangerous designs, so too failure-to-warn law requires them to provide clear, comprehensive, accurate information that is not encumbered by distractions or confusions, and that is presented with sufficient urgency and prominence. In the language of state tort law, manufacturers are required to

provide *adequate* warnings about their products' dangers.[2]

For two reasons – one of principle, and one of policy – the provision of adequate warnings is an especially important issue in the prescription drug context. First, as a matter of principle, because pharmaceuticals are typically administered in connection with medical treatment, this area of a failure-to-warn law bears a close resemblance to the "informed consent" branch of medical malpractice law. *See Canterbury v. Spence*, 464 F.2d 772, 780 & n.15 (D.C. Cir. 1972). The ingestion of a drug implicates one's right to control what goes into one's body. Yet, the invasiveness that comes with the use of drugs is, of course, what renders them immensely valuable. The law of informed consent, which addresses the same invasiveness/health tradeoff in the context of decisions to undergo surgeries and other medical procedures, squares this circle by requiring physicians to make full disclosure of material information and by having judges and juries scrutinize these disclosures carefully. Likewise, in failure-to-warn law as applied to prescription drugs, adequacy of disclosure is crucial to ensuring that drug

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[2] Some states recognize failure-to-warn claims that sound in negligence rather than strict products liability. The differences, if any, between the two causes of action are for most purposes modest. When suit is brought for negligent failure-to-warn, the same adequacy issue arises, though here it is framed as the question of whether the defendant failed to provide the warnings and information that a reasonably prudent manufacturer would have provided. *See, e.g., Winter v. Novartis Pharm. Corp.*, 882 F. Supp. 2d 1113, 1117-18 (W.D. Mo. 2012) (describing the standard for adequate warning under Missouri negligent failure-to-warn law), *aff'd*, 739 F.3d 405 (8th Cir. 2014). Accordingly, this brief will treat strict products liability and negligent failure-to-warn claims interchangeably.

users gain access to valuable products, but on terms that duly protect their bodily integrity and safety.

Second, courts have long appreciated that design-defect law fits pharmaceutical products awkwardly. This is not only because the dangers of many drugs, like their potential benefits, are substantial. It is also because the health risks of a drug may outweigh the benefits for some subset of consumers even though there is another subset of consumers for whom the benefits outweigh the risks. Liability for design defect for pharmaceutical products – if it leads manufacturers to take certain products off the market – thus poses the risk that a minority of consumers who would greatly benefit from a drug lose access to it because some other group of consumers would not benefit from it. The rational policy solution to which the common law has largely converged is to diminish design-defect liability for prescription drugs while keeping failure-to-warn liability in place. *See, e.g.*, RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(c) (1998) (adopting a special and highly restrictive test for design defect for prescription drugs, under which a drug is defectively designed only if a reasonable health-care provider, knowing of a drug's foreseeable risks and benefits, would not prescribe the drug for *any* class of patients). These same considerations make it all the more important that drug manufacturers provide adequate warnings and information about their products. The primary way in which tort law promotes drug safety is by requiring manufacturers to provide adequate information of the risks posed by their drugs.[3]

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[3] The learned intermediary rule that applies to failure-to-warn claims concerning prescription drugs in no way diminishes

As noted, a failure-to-warn case turns fundamentally on whether the product in question lacked "adequate" warnings and thereby was rendered unduly dangerous. Under state law, adequacy is a function of the accuracy and completeness of the information accompanying a product, as well as the prominence, clarity, and urgency with which that information is presented. Although there is some variation in how different states have defined adequacy (which is part of why federalism *is* truly in play in this case), the variation is not vast.

In their products liability law treatise, Professors Owen and Davis summarize the relevant principles as applied to prescription drugs in particular:

> The principles of adequacy applicable to warnings generally . . . apply to prescription pharmaceuticals. All material information on possible risks must be conveyed to the relevant medical care provider and be comprehensible to the specialist as well as the general practitioner. The sufficiency of the seller's discharge of its informational obligation is measured in terms of whether the cautionary information conveys the nature, the scope, and the severity

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the importance of adequate warnings. Prescription drugs reach the consumer through his or her treating physician. By requiring a drug company to directly warn only the treating physician, the learned intermediary rule shifts the target of the warning from a consumer, who might lack the knowledge and the appreciation of context necessary to interpret it, to the physician, who is presumed to have both. Simply put, doctors have the professional expertise and responsibility to read, absorb, and convey warnings, and they face legal liability for not doing so. That physicians are expected to take manufacturers' warnings very seriously in informing, advising, and treating their patients makes "adequacy" more important, not less so.

> of the risk, together with a plain statement of how the user may avoid such risks and safely use the product.

2 DAVID G. OWEN & MARY J. DAVIS, OWEN & DAVIS ON PRODUCTS LIABILITY § 19:14 (4th ed. May 2018 Update) ("OWEN & DAVIS") (footnote omitted).

A bare mention of a general class of risks associated with a prescription drug does not satisfy the requirement of adequacy. Instead, a drug's warning must accurately and clearly describe the conditions under which the relevant risks might be realized, the precise complications that might result from the realization of such risks, and the consequences for patients of a failure to heed the warning. Moreover, this information must be communicated in a manner that is likely to alert a reasonably prudent prescribing physician to the danger. As the Ohio Supreme Court has explained:

> The fact finder may find a warning to be unreasonable, hence inadequate, in its factual content, its expression of the facts, or the method or form in which it is conveyed. The adequacy of such warnings is measured not only by what is stated, but also by the manner in which it is stated. A reasonable warning not only conveys a fair indication of the nature of the dangers involved, but also warns with the degree of intensity demanded by the nature of the risk. A warning may be found to be unreasonable in that it was unduly delayed, reluctant in tone or lacking in a sense of urgency.

Seley v. G.D. Searle & Co., 423 N.E.2d 831, 837 (Ohio 1981) (citation omitted). As the previous citation indicates, the adequacy question is usually for the

jury. *Id.* *See also* OWEN & DAVIS § 19:14 (question of adequacy is for the finder of fact).

Whatever the precise standard of adequacy applied in a given jurisdiction, it is abundantly clear that a drug manufacturer's mere mention of its product's dangers (on a product label or in a package insert) is insufficient to satisfy state tort law and avoid liability. Indeed, examples abound of instances in which manufacturers have faced liability for warnings that, while mentioning the relevant health risk, did so in a way that *inadequately* warned of the risk. *See, e.g.*, *Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378, 1387 (4th Cir. 1995) (applying Virginia law) (jury issue presented on whether manufacturer was required to warn of health risks from use of acetaminophen in combination with alcohol); *Guenther v. Novartis Pharm. Corp.*, 990 F. Supp. 2d 1299, 1303-06 (M.D. Fla. 2014) (applying Florida law and affirming a jury finding of liability in a failure-to-warn case alleging injuries caused by bisphosphonate); *Winter*, 882 F. Supp. 2d at 1117-20 (applying Missouri law and finding sufficient evidence for jury on failure-to-warn negligence case involving bisphosphonate); *Michael v. Warner/Chilcott*, 579 P.2d 183, 187 (N.M. Ct. App. 1978) (pharmaceutical product's warning that product "may damage the kidneys" presents jury issue on adequacy).

B. Petitioner's Proposed Warning to FDA Bears All the Hallmarks of an Inadequate Warning

As explained in detail in Respondents' merits brief, the proposed language submitted by Petitioner to FDA – in the best case – failed to provide a clear articulation of the risk of atypical femoral fracture associated with its drug. Petitioner's proposed language confusingly associated a particular and grave risk

(the risk of atypical femoral fracture) with a distinct and distinctly less grave risk (the risk of minor stress fractures of the sort that are normally cured by rest). In fact, Petitioner's proposed language was even more problematic, for it added that "stress fractures with similar clinical features also have occurred in patients not treated with bisphosphonate." JA707. This statement compounded the false equivalence of atypical femoral fractures and garden-variety stress fractures. The latter typically occur in younger people as a result of athletic activity. C.A.App. 1573. That is not a population that typically suffers from osteoporosis. In asserting that the majority of (garden-variety) stress fractures seen by physicians appear in patients who are not taking bisphosphonate, Petitioner's proposed language further diluted what little information it might otherwise convey about the risk to users of its product of atypical femoral fractures.

Even assuming for purposes of argument that there is a biological link between stress fractures and atypical femoral fractures (making it arguably appropriate to mention both in the same label), the particular way in which Petitioner's proposed label associated these two very different injuries has an obvious potential to distract and confuse. Language that is cluttered, that conflates more serious with less serious risks, that "buries the lede," or that is otherwise prone to misinterpretation is at the very core of the adequacy issue in failure-to-warn litigation. As noted above, the question in such cases often is not whether *any* warning was given, but whether the warning that was given was *adequate*. And it is precisely the characteristics on display in Petitioner's proposed language that would support a finding of inadequacy.

C. FDA's Rejection of a Proposed Label That Merely Mentions a Risk of Injury Cannot Be the Basis for an Implied Preemption Defense Based on "Impossibility"

Petitioner's argument boils down to this: FDA's rejection of a proposed label that plainly could be deemed to provide inadequate warnings under state tort law nonetheless suffices to establish that it would not have approved a clearer, stronger, and more obviously adequate warning. This argument comes in two variants: one is that the mere rejection of a proposed label mentioning the risk suffices to ground impossibility preemption (the "mere rejection" version), and a second is that the rejection of the proposed label provides evidence of further facts, which themselves ground impossibility preemption (the "further facts" version).

As shown below, Petitioner's argument fails whether on the "mere rejection" version or the "further facts" version. Needless to say, Petitioner should not be able to claim its prize of implied preemption by toggling between these two versions, either. In the end, however, the reason neither version works is basically the same: Merck's confusion of atypical femoral fractures with much different and much less serious "stress fractures" rendered its proposed warning the very opposite of what patients and their physicians need from a warning. That is why the warning might well be deemed inadequate by a jury applying the common law of torts; it is also why FDA rejected Merck's warning.

1. *The Mere Fact of FDA's Rejection of Petitioner's Proposed Label Cannot Suffice To Establish Impossibility*

As indicated, Petitioner's proposed label mentioned in an oblique, anything-but-clear manner the risk of atypical femoral fracture associated with the use of Fosamax. FDA rejected this label. There is at least a suggestion from Petitioner and supporting *Amici* that these facts alone suffice to establish impossibility preemption – that FDA's rejection of a proposed drug label that *in some manner mentions* the relevant risk establishes that FDA would have likewise rejected *any attempt* to warn of that risk.

Such a suggestion is obviously untenable. To establish the defense of federal preemption, a defendant in a failure-to-warn case such as this one must prove that it was *impossible* to rectify the deficiencies in its warning under state law because federal law clearly prevented it from doing so. *See Levine*, 555 U.S. at 569. The fact that FDA rejected a warning that a jury would surely be entitled to deem inadequate in no way suggests that the defendant was *unable to issue an adequate warning*, for there is no reason to suppose that federal law rendered Petitioner unable to provide an adequate warning as to the danger of atypical femoral fractures. FDA's rejection of a proposed drug label leaves the manufacturer completely at liberty to propose or add a better warning. A drug manufacturer thus does not establish that it was blocked by federal regulatory law from complying with state failure-to-warn law simply by showing that its proposed warning was rejected. Again: such a showing quite obviously leaves open the possibility that a clearer or more compelling warning – one that

would have been adequate and thus avoided liability – would not have been rejected by FDA.

This version of Petitioner's impossibility argument is practically pernicious, not just conceptually unsound. Were it adopted, prescription drug manufacturers would have available to them a simple formula for avoiding liability for failures to warn about previously unknown or underestimated risks. Essentially, all that they would need to do to enjoy the shield of federal preemption is to propose a tepid and inadequate warning. Not only would the acceptance of this argument thus reward subterfuge, it would result in a severe encroachment onto traditional state tort law without any corresponding benefit to a federal regulatory regime that aims to ensure that prescription drugs are properly labeled.

2. *Defendant Cannot Bear the Burden Set Forth in* Levine *of Showing That a Proposed Label That Contains an Adequate Warning Would Have Been Rejected by FDA*

As just demonstrated, there cannot be impossibility preemption merely on a showing of FDA's rejection of a proposed label that facially mentions the relevant risk. In this context, the impossibility question instead concerns whether it would have been possible for Petitioner to adopt a warning that would be deemed adequate under state tort law and that FDA would not reject. If it would have been possible, then there cannot be impossibility preemption.

As explained in *Mensing*, this Court's prior decision in *Levine* places on the manufacturer the burden of establishing clearly that it would have been barred by FDA from giving an adequate warning: "The Court in [*Levine*] asked what the drug manufacturer could

independently do under federal law, *and in the absence of clear evidence that Wyeth could not have accomplished what state law required of it*, found no pre-emption." 564 U.S. at 624 n.8 (italics added). Only a manufacturer that can clearly establish that FDA would have rejected a proposed *adequate* label stands to obtain the protection afforded by the demanding defense of impossibility preemption. A manufacturer whose proposed warning is rejected for other reasons *can* "accomplish[] what state law require[s] of it" by providing an adequate warning, and can do so "independently." *Id.*

As Respondents' brief establishes, this is the very position Petitioner was in. Contrary to Petitioner's contention, FDA's plain language in its rejection of the proposal concerned the running-together of atypical femoral fractures and ordinary stress fractures, not whether there was a scientific basis to justify some strengthening of the existing warning of the association between atypical femoral fractures and long-term bisphosphonate use.

The Court's analysis of the record in *Levine* itself highlights the weakness of this variant of Petitioner's implied preemption argument. Diana Levine lost her arm when an IV-push injection of Phenergan entered her artery. *Levine*, 555 U.S. at 559. She claimed that the labeling of Phenergan inadequately warned of the risks of IV-push administration as opposed to the use of IV-drip or some other method. *Id.* at 564-65. Justice Alito's dissenting opinion reviewed in detail the relevant FDA-approved label, noting that FDA had expressly considered whether to prohibit IV-push as a method of administration but had not done so, and had instead approved warnings with respect to that method of administration. *Id.* at 613-17 (Alito,

J., dissenting). Instead, the label warned that "**INADVERTENT INTRA-ARTERIAL INJECTION CAN RESULT IN GANGRENE OF THE AFFECTED EXTREMITY.**" *Id.* at 618. According to Justice Alito, it was thus "demonstrably untrue" that, in 2000 (when Phenergan was administered to Levine), its "labeling did not contain a specific warning about the risks of IV-push administration." *Id.* at 619.

The majority and dissent parted ways concerning what had happened 12 years earlier, in 1988. They agreed that Wyeth had proposed "different language for Phenergan's warning about intra-arterial injection" and that FDA had rejected the proposal. *Id.* at 572 n.5 (majority); *id.* at 605 n.1 (Alito, J., dissenting). The dissent emphasized plaintiff's admission that the 1988 proposal would have prevented Ms. Levine's injury by requiring the IV-drip method, rather than allowing IV-push administration, and argued, therefore, that Wyeth "*did* propose an adequate warning." *Id.* at 605 n.1 (Alito, J., dissenting). By contrast, the majority acknowledged the plaintiff's admission, but relied on findings that the proposed warning was not substantively different than the existing warning in holding that this situation did not result in a preemptive conflict. *Id.* at 572 n.5.

It is undisputed that, for Phenergan, Wyeth had proposed an added warning addressing the exact risk at issue and that FDA had rejected the proposed warning. Although the majority and dissent disagreed as to whether the proposed warning was substantively different from the existing warning, six members of this Court found that FDA's rejection of a proposed warning addressing the same method of administration that injured Ms. Levine failed to provide a sufficient basis on which to displace state failure-to-

warn law. This was much "clearer evidence" of a preemptive regulatory act than FDA's rejection of Wyeth's proposed warning with respect to Fosamax. The *Levine* Court obviously understood that the issue was not whether there was a proposal and rejection of a warning that facially concerned the relevant risk – indisputably, there was – but whether the proposed warning that FDA rejected was *adequate*. *Id.* at 572 ("[Wyeth] does not argue that it attempted to give the kind of warning required by the Vermont jury but was prohibited from doing so by the FDA."). Evidence of a rejection of an *adequate warning* is the "clear evidence" that was missing in *Levine*, *id.* at 571-72, and is likewise missing in the case at bar.

The actual proposal and rejection in *Levine* removed that case from the "hypothetical" or "counterfactual" realm. *See Mensing*, 564 U.S. at 624 n.8. Furthermore, the warning that FDA rejected in *Levine* was quite obviously *stronger* than the one Merck proposed regarding the risk of atypical femoral fractures in the case at bar. The irony of Petitioner's current position is apparent. Even though this Court concluded in *Levine* that Wyeth could constitutionally be subject to failure-to-warn liability despite the fact that its proposed warning was actually rejected by FDA, and despite the fact the warning that it did give was comparatively clear and strong, it now asks the Court to immunize it entirely from liability on the basis of the agency's rejection of a considerably less clear and compelling warning.

III. STATES HAVE AMPLE RESOURCES WITHIN TORT LAW TO KEEP FAILURE-TO-WARN TORT LITIGATION IN CHECK

Petitioner paints a picture of a world in which state tort law leaves drug companies unprotected from the whims of uninformed citizen juries. The real world is nothing like that.

A. Counterfactuals

Petitioner and the government claim that a jury should not decide whether the *Levine* exception was met because that exception presents a question of law. As the Third Circuit recognized, however, this Court's articulation of the exception indicates that it is a question of fact. *See Levine*, 555 U.S. at 571. Of course, Petitioner might mean "question of law" in a conclusory way; they might mean that *juries should not be permitted to* decide whether a defendant has proved that FDA would have rejected a proposed warning (even if it is in essence a question of fact in every particular case). That is presumably why much of Petitioner's brief seems to relate to juries.

Petitioner pours a lot of energy into trying to incite fears of juries. *E.g.*, Pet. Br. 40 (describing "practical nightmare" of permitting multiple juries to use their "'intuitions'"). The fear is inappropriate, given the centrality of the right to jury trial to our legal system, as evidenced by its enshrinement in the federal and state constitutions. U.S. CONST. AMENDS. VI, VII. More to the point, the Federal Food, Drug, and Cosmetic Act itself provides that juries determine whether a drug is "misbranded" based on an inadequate warning. *See* 21 U.S.C. §§ 331(a), 332(b), 334(b), 352(a), (f); *Levine*, 555 U.S. at 570 ("the statute contemplates that federal juries will resolve most misbranding claims"). Juries play an integral role

in the *federal* system, and Congress itself expressed confidence in juries' ability to evaluate warnings on prescription drugs.

Petitioner foments distrust of juries in its repeated use of the term "counterfactual," which appears a whopping 13 times in its brief. The insinuation is that our legal system courts disaster by allowing juries to conduct an inquiry of the form "What would have happened if the defendant had done what the plaintiff contends it should have done, but did not do?" Petitioner's hyperbolic language about "counterfactual quagmires" not only insults the venerable institution of the jury but also displays disregard for basic tort law that is taught each year to 1Ls around the country. Typically – in what many lawyers would regard as a *pro-defendant* treatment of cause-in-fact doctrine when compared to treatments that emphasize the more open-ended language of "substantial factor" – students are taught: (a) *the jury* ordinarily decides the question of cause-in-fact in a negligence or products liability case; (b) cause-in-fact is usually determined by the *but-for* test; and (c) the but-for test requires the jury to decide what would have happened if the defendant had not acted negligently or had not sold a defective product. On this traditional approach, *a counterfactual question* lies at the very heart of the jury's role. It is emblematic of Petitioner's eagerness for the Court to forget state tort law that it suggests, bizarrely, that juries are incapable of handling questions with which they are routinely entrusted.

Of course, there are limits on the issues that juries should decide. State judges and legislators possess and implement many devices to constrain jury discretion, reflecting the considered judgment of a particular state's government concerning how these cases should proceed. Proper determination of the

question of fact comes only after proper instruction on the applicable law, as well as vetting to ensure that submission of the question is proper in the first instance. This is a basic principle of state law as well as federal law. *See, e.g., CSX Transp., Inc. v. McBride*, 564 U.S. 685, 704 (2011) ("Properly instructed on negligence and causation, and told, as is standard practice in FELA cases, to use their 'common sense' in reviewing the evidence, juries would have no warrant to award damages in far out 'but for' scenarios. Indeed, judges would have no warrant to submit such cases to the jury.") (citation omitted). There are also myriad protections to ensure that only appropriate questions reach the jury in the first instance.

B. State Tort Law Provides Multiple Layers of Protection To Respect Federal Regulation and To Prevent Jury Determination of Unwarranted Questions

Defendants in failure-to-warn cases enjoy the same general protections available in other suits. For example, this Court established heightened pleading requirements in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009). These requirements certainly apply to federal courts sitting in diversity and can lead to dismissal on the pleadings. *See, e.g., Anderson v. Abbott Labs.*, No. 3:11-CV-1825-L, 2012 WL 4512484 (N.D. Tex. Sept. 30, 2012) (dismissing claims of failure to warn of the association between the rheumatoid arthritis drug Humira and pediatric leukemia). Claims in which there are no genuine issues of material fact are subject to summary judgment. And courts can correct error post-trial with motions for judgment as a matter of law, motions for new trial, and appeals. In addition to such general protections, however, states have put in place three targeted protections for failure-to-

warn cases that respect the prescribing physician's expertise, defer to appropriate judgments by FDA, and guard scientific integrity.

1. *Prescribing Physician/Learned Intermediary*

Failure-to-warn cases involving prescription drugs have a unique feature that enables juries to assess with considerable reliability the existence and causal significance of an omitted adequate warning. Barring some extraordinary circumstance, there will be sworn testimony, either live or by deposition, of the prescribing physician. This provides an actual look at how a particular warning functioned in the real world.

For many decades, the overwhelming majority of state courts have applied the "learned intermediary doctrine" in prescription drug cases. They have held fast to this rule even in the face of criticism and a few prominent decisions questioning it. According to this doctrine, a drug company generally has no duty to warn a patient directly, but can discharge its duty by giving an adequate warning to the physician. The products liability provisions of the Third Restatement of Torts summarize the doctrine as follows:

> (d) A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:
>
> > (1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or
> >
> > (2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to

> reduce the risks of harm in accordance with the instructions or warnings.

RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d). "The rationale supporting this 'learned intermediary' rule is that only health-care professionals are in a position to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a given form of prescription-based therapy." *Id.*, cmt. b.

The prescribing physician is always a critical witness. His or her testimony gives real-world insight into the adequacy of a warning as interpreted by an actual physician. But this testimony can also end the litigation as a matter of law. Generally, unless the prescribing physician testifies that a different warning would have made a difference – by causing the physician to modify the prescription, to give the patient additional warnings, or not to prescribe the drug at all – the drug company will file a motion for summary judgment based on lack of causation, and some courts will deem such evidence sufficient to justify granting the motion. *See, e.g., In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, 639 F. App'x 874, 878 (3d Cir. 2016) ("[s]ummary judgment is properly granted on a failure to warn claim where the record 'is devoid of evidence to support [the] argument that a different warning would have altered [the physician's] prescribing methods'") (citation omitted; first alteration added).

2. *Regulatory Compliance*

Because FDA regulates prescription drugs, virtually every drug company in a failure-to-warn case emphasizes at trial that it operates within a regulated industry; that it cannot distribute a drug until FDA

approves it; and that FDA has approved the drug's label. The Third Restatement of Torts puts forward the principle that, while compliance with safety statutes and regulations is proper for a jury to consider with respect to certain risks, *see* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4(b), the "traditional view" is that such regulations "provide only minimum standards." *Id.* § 4 cmt. e ("Thus, most product safety statutes or regulations establish a floor of safety below which product sellers fall only at their peril, but they leave open the question of whether a higher standard of product safety should be applied.").

As is characteristic of our federal system in the domain of torts, however, there is variation among the states, and some have enacted – not without controversy – statutes incorporating a regulatory compliance defense, or giving greater weight to evidence of compliance than is traditionally given under common law rules. *See, e.g.*, ARK. CODE ANN. § 16-116-205; COLO. REV. STAT. § 13-21-403; FLA. STAT. § 768.1256; IND. CODE § 34-20-5-1; KAN. STAT. ANN. § 60-3304(a); MICH. COMP. LAWS § 600.2946(4); N.J. STAT. ANN. § 2A:58C-4; N.D. CENT. CODE § 28-01.3-09; TENN. CODE ANN. § 29-28-104; TEX. CIV. PRAC. & REM. CODE ANN. § 82.007; WASH. REV. CODE § 7.72.050(2). Such statutes reflect a policy choice by these jurisdictions to dampen certain forms of tort liability and litigation. These states' erection of new barriers to tort liability is a further reason that the doctrinal tool Petitioner hopes the Court will create here is neither necessary nor constitutionally appropriate.

3. *Scientific Reliability*

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 597 (1993), this Court held that Federal

Rule of Evidence 702 assigns district judges the role of "gatekeep[ers]" who must screen scientific evidence to ensure its reliability. "Post-*Daubert*, the federal district courts, exercising their newly appointed 'gatekeeper' function, have scrutinized expert testimony more closely, often holding rigorous pre-trial '*Daubert* hearings' – that are often outcome determinative – to determine the admissibility of proffered expert testimony." David G. Owen, *A Decade of Daubert*, 80 DENV. U.L. REV. 345, 362 (2002).

The majority of states have now adopted some form of that standard, with the result that almost every failure-to-warn case includes a separate proceeding within the overall litigation to determine scientific reliability and the consequent admissibility of expert testimony. This can be a major hurdle for failure-to-warn plaintiffs. *See, e.g.*, *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prods. Liab. Litig.*, 892 F.3d 624, 632-45 (4th Cir. 2018) (no abuse of discretion in excluding three of plaintiffs' experts under *Daubert*, effectively dismissing more than 3,000 claims); *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 795-800 (3d Cir. 2017) (no abuse of discretion in excluding plaintiffs' expert and granting summary judgment, effectively disposing of 315 claims). Again, recognition of an existing and effective check on liability belies Petitioner's overblown claims about the pressing need for a federal-law immunity from liability.

CONCLUSION

State tort law requires prescription drug manufacturers to provide adequate warnings of their drugs' harmful side-effects. Nothing in federal law prohibits manufacturers from providing such warnings and thus avoiding liability. Nor is there any reason to believe that state courts are administering failure-to-warn law in a way that threatens the sort of interference with federal interests that might justify further federal-court oversight to rein them in. For the past 80 years – since moving from *Swift v. Tyson* to *Erie Railroad Co. v. Tompkins* – this Court has kept out of the business of shaping the precise contours of state tort law. Consistent with this commitment, the Court declined to interfere with state failure-to-warn claims against brand-name drug manufacturers almost a decade ago in *Wyeth v. Levine*. In today's case, Petitioner invites the Court to engage in an untethered form of implied preemption analysis, in effect, asking the Court to abandon the balanced and sensible position it staked out in *Levine*. When the content of state failure-to-warn law is adequately recognized and the defendant-protective resources of today's state tort law are fully appreciated, it becomes apparent that federalizing this area of law is neither necessary nor appropriate.

Respectfully submitted,

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